

To whom it may concern:

My personal views/biases and comments:

Section 1.1 - regarding the general discussion of COI Committees and how they interact, it is unfair to instruct institutions in how to deal with financial COI and the IRB. Consideration should be given, yes - but directing the institution, no. The IRB is not equipped to deal with these issues. The COI should determine how the issue is managed and whether or not the IRB should be informed.

Section 1.3 - I disagree. That may be true in a few places but such generalizations are unfair.

Section 1.5 - Institutions should be reminded of the PHS directive but then should be told to consider including financial COI to this educational program. This is an institutional decision.

Section 2.2 is confusing.

Section 3.1 0 all conflict of interest not just financial should be considered. In fact, institutions and IRBs should consider writing a conflict of interest policy that encompasses both financial and non-financial COIs.

Sections 4.1 and 4.2 The COI committee and not the IRB should determine when a COI has occurred and that it has met the threshold for informing the IRB. The IRB should then consider whether or not and how subjects should be informed of this COI.

Section 4.3 all bullet points should be considered by the COI Committee and not the IRB.

Section 4.4 the COI committee should consider these issues and inform the IRB. The IRB can then best determine how subjects should be informed.

Section 5.2 after COI review and recommendation, the IRB should be notified of the potential conflict. The IRB will then decide if, when and how potential subjects should/will be notified of these conflicts.